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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,840	09/13/2000	Paul Remijan	2476.1003-001	7821

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EXAMINER	
LEUBECKER, JOHN P	
ART UNIT	**PAPER NUMBER**
3739	14

DATE MAILED: 03/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/660,840	REMIJAN ET AL.	
	Examiner	Art Unit	
	John P. Leubecker	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) *19-21,34,40-50,52-58 and 70-80* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,22-33,35-39,51 and 59-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-3, 5, 6, 9, 12, 15, 17, 18, 22-24, 28-31, 35, 36, 39, 51, 59-62 and 65-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. (U.S. Pat. 5,423,312) in view of Yoshida et al. (U.S. Pat. 4,593,973).

As to claims 1 and 51, Siegmund et al. discloses a rigid optical waveguide (1) having a light absorbing layer (7), a handle (3,27) attached to the optical waveguide, an optical element (5) coupled to the distal end of the waveguide, an optical relay (17) mounted in the handle (Fig.1) and optically coupled to a proximal end of the waveguide, and an imaging device (CCD camera) mounted in the handle at a proximal end of the optical relay. Siegmund et al. fails to specify the diameter of optical waveguide. However, analogous miniature endoscopes are known to be of a diameter as small as 0.7 mm as taught by Yoshida et al. (note col. 4, lines 4-6). It would have been obvious to one of ordinary skill in the art to have made the endoscope (and thus the waveguide) any desired diameter to meet the particular requirements for a certain procedure (i.e., dental). Therefore, making the endoscope of Siegmund et al. a diameter so as to require the waveguide to be less than 2 mm would be obvious.

Clearly the above mentioned position would also apply to claims 2 and 3. As to claim 5, 6, 30 and 31, the waveguide comprises a high-index glass rod of a refractive index greater than 1 (which includes 1.6). As to claim 9, note col.4, lines 3-8. As to claims 12 and 60, note ring of optical fibers (25) which forms a sheath. As to claims 18 and 65, the insertion section as

describe above would form a needle, as broadly as claimed. As to claim 22, an image from a CCD camera is inherently viewed on a display. As to claim 23, note that optical fibers (25) are optically coupled to a light source in the handle (note coupling point 43). As to claim 24, note coupling 39. As to claim 59, note optical fibers (41). As to claims 61 and 62, note col.4, line 27. As to claim 66, note col.4, lines 47-52 as to the cannula. As to claims 67 and 68, note col.6, lines 17-26 regarding a locking mechanism (70).

As to claim 28, Siegmund et al. further fails to disclose the particulars of the illumination channel as claimed. Particularly, Siegmund et al. discloses a circular arrangement of individual optical fibers and thus fails to disclose an illumination channel having a first layer on an inner surface and a second layer on an outer surface. However, Yoshida et al., as pointed out in the previous Office Action, teaches such structure (note col.2, line 68 to col.3, line 9) to avoid the drawbacks of the structure taught by Siegmund et al. (Yoshida, col.1, lines 27-47). It would have been obvious to one of ordinary skill in the art to have provided the illumination channel taught by Yoshida et al. in the Siegmund et al. device for the benefits taught by Yoshida et al. The claimed features of claims 29-31, 35, 36 and 39 are addressed above.

3. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Woodard et al.. (U.S. Pat. 5,947,958).

Although the different distal tip configurations (71,72, Figs. 8b,8c) of Siegmund et al. provide dispersive properties and could be considered as a "ring", Woodard et al. explicitly teach that, in an alternative to forming the tip, that other dispersive elements including lenses and refractive gradients could be used (col.5, lines 39-44). Thus, it would be obvious to one of

ordinary skill in the art to have used a separate dispersive element in the device of Siegmund et al. as an obvious design alternative for dispersing the illumination light.

4. Claims 7, 10, 13, 14, 16 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al.

As to claims 7 and 10, Siegmund et al. fails to specify the thickness of the light absorbing layer and the wall thickness of the illumination channel. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of these layers (Applicant discloses the claimed ranges simply as preferred), the choice of such thicknesses would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and thicknesses in the claimed ranges are not extraordinary in the art, such claimed ranges would be considered obvious and desirable.

As to claim 13, Siegmund et al. explicitly teaches that the outer sheath can be made from metals or plastics (col.5, lines 2-3) but fails to specify polyamide. If not inherently encompassed by "plastics", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. Polyamide is a well known plastic material. It would therefore be obvious to one of ordinary skill in the art to have used polyamide. Evidence that polyamide is a well known plastic material will be provided only if Applicant disagrees on record to such notice.

As to claim 14, Siegmund et al. fails to mention the thickness of the outer sheath. However, inasmuch as neither Applicant nor the prior art of record attribute any significance to the precise thickness of the sheath (Applicant discloses the claimed ranges simply as preferred), the choice of such thickness would have been obvious to the artisan if routine experimentation proved such to be suitable. Where the instant specification and evidence of record fail to attribute any significance (novel or unexpected results) to a particular arrangement, the particular arrangement is deemed to have been a design consideration within the skill of the art. In re Kuhle, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975). Since miniaturization is a key design consideration in the non-invasiveness of endoscopic devices and the claimed is not extraordinary in the art, such claimed thickness would be considered obvious.

As to claim 16, Siegmund et al. fails to disclose the material of the lens. Both glass and plastic lenses are notoriously well known in the art. Either can be used for the same purposes and both have advantages and disadvantages. It would have been obvious to one of ordinary skill in the art to have used plastic for the material of the lens of Siegmund et al. as a matter of design choice.

As to claim 32, Siegmund et al. fails to disclose the specific properties of the high index of refraction glass rod (i.e., that it is an F2 or F7 glass). If not inherently encompassed by "high index of refraction glass", Siegmund's teaching would prompt one of ordinary skill in the art to draw from common knowledge. F2 and F7 glasses are well known types of glass. It would have therefore be obvious to one of ordinary skill in the art to have used well known types of glass such as F2 and F7 glass. Evidence that these are well known types of glass will be provided only if Applicant disagrees on record to such notice.

5. Claims 8 and 33 rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Eastman (U.S. Pat. 5,319,731).

Siegmund et al. disclose the device as described above wherein the light absorbing layer is a hydrogen-fired blackened surface and thus fails to disclose such layer as being comprised of extramural absorption glass. Since such extramural absorption glass is known to provide similar properties (e.g., attenuate stray light) (note Eastman, col.1, lines 46-65 and col.5, lines 35-53), it would have been obvious to the skilled artisan to have used extramural absorption glass for the absorption layer as an obvious design alternative. Use of such absorption glass would simplify the application of the absorbing layer by eliminating the hydrogen-firing process while still providing good image quality.

6. Claims 11, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Strack (U.S. Pat. 3,902,880).

Since Siegmund et al., as described above, does not mention any specific optical properties, one of ordinary skill in the art would draw from conventional knowledge in the art when reducing such device to practice. Strack evidences that illumination core materials can have a refractive index of 1.5 to 1.81 (col.3, lines 12-17) with the refractive index of the cladding (which is analogous to the first and second layers of claim 38) being lower. The claimed ranges are inherent properties of typically known materials (e.g., glasses, plastics) that have been used for the same purposes (e.g., illumination). Clearly, such specific optical properties would be

obvious to one of ordinary skill in the art as they are inherent in the materials that would conventionally be used.

7. Claims 25, 26, 63 and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Kurtzer (U.S. Pat. 5,168,863).

Siegmund et al. fails to disclose a sterile disposable sheath attached to the probe and extending over the handle. However, Kurtzer teaches an analogous endoscope having such sheath (20). It would have been obvious to one of ordinary skill in the art to have provided a sheath over the handle of Siegmund et al. to provide a sterile barrier between the handle/camera and the patient to protect the patient from any contamination from elements of the device which are normally handle by the surgeon and to protect the handle/camera from contamination from the patient (e.g., fluids, bacteria).

8. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Jones (U.S. Pat. 3,724,922).

Siegmund et al. disclose a separate optical channel and thus fails to disclose a light source optically coupled to the imaging channel. Jones teaches that a combined imaging and illumination channel has been contemplated. It would have been obvious to one of ordinary skill in the art to have combined the channels (i.e., optically coupled the light source to the imaging channel) so as to simply the device and eliminate the need for separate optical fibers which add to the dimension of the device.

9. Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Siegmund et al. in view of Yoshida et al. and further in view of Kishi et al. (U.S. Pat. 4,972,827).

Although claim 69 further recites a "stylet" which could be anticipated by a cannula, it appears from the specification that Applicant is using the term "stylet" to define what is commonly referred to as an obturator. Kishi et al. shows what is conventionally known in the art: a cannula (trocar) which eventual receives the endoscope is inserted through tissue with the aid of an obturator (note col.1, lines 22-34). It would have been obvious to one of ordinary skill in the art to have provided a trocar/obturator with the Siegmund et al. device to aid in insertion of the endoscope into the body.

Response to Arguments

10. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Kim et al. (U.S. Pat. 5,754,716)—note use of EMA glass to eliminate stray light and improve image transmission (col.7, lines 2-15).

Sauer et al. (U.S. Pat. 5,467,762)—note state of art with respect to trocar/obturator/endoscope combination.

Tashiro (U.S. Pat. 4,790,295)—note light dispersive ring.

Okada (U.S. Pat. 5,601,525) and Colvin et al. (U.S. Pat. 6,498,884)—note light absorbing layer.

Leiter (U.S. Pat. 1,692,554) and Bonne et al. (U.S. Pat. 6,306,083)—note combined illumination and imaging channel.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Leubecker whose telephone number is (703) 308-0951. The examiner can normally be reached on Monday through Friday, 6:00 AM to 2:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

John P. Leubecker
Primary Examiner
Art Unit 3739

jpl